# HEALTH

# Study: Vaccine blocks cervical cancer

## '100 percent efficacy' against cancer-causing virus, maker says

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**TRENTON, New Jersey (AP) -- The first major study of an experimental vaccine to prevent cervical cancer found it was 100 percent effective, in the short term, at blocking the disease and lesions likely to turn cancerous, drug maker Merck & Co. said.**

Gardasil, a genetically engineered vaccine, blocks infection with two of the 100-plus types of human papilloma virus, HPV 16 and 18. The two sexually transmitted viruses together cause about 70 percent of cervical cancers.

Other types of HPV also can cause cervical cancer and painful genital warts. About 20 million Americans have some form of HPV.

The final-stage study of Gardasil included 10,559 sexually active women ages 16 to 26 in the United States and 12 other countries who were not infected with HPV 16 or 18. Half got three vaccine doses over six months; half got dummy shots.

Among those still virus-free after the six months, none who received the vaccine developed cervical cancer or precancerous lesions over an average two years of follow-up, compared with 21 who got dummy shots.

"To have 100 percent efficacy is something that you have very rarely," Dr. Eliav Barr, Merck's head of clinical development for Gardasil, told The Associated Press. "We're breaking out the champagne."

The study, which was funded by Merck, was to be presented Friday at a meeting of the Infectious Diseases Society of America.

A second analysis, including hundreds more women participating in the ongoing study, showed that after just one dose the vaccine was 97 percent effective. That analysis found only one of the 5,736 women who got the vaccine developed cervical cancer or precancerous lesions, compared with 36 among the5,766 who got dummy shots.

Barr said the 97 percent rate was more "real world," given that patients sometimes miss or delay follow-up shots or tests.

"I see this as a phenomenal breakthrough," said Dr. Gloria Bachmann, director of The Women's Health Institute at Robert Wood Johnson Medical School in New Brunswick.

Bachmann said diagnosis of infection leaves women anxious over the heightened risk of cervical cancer and raises questions among couples about infidelity and prior sexual activity.

"You have to get students in grammar school, middle school, high school (vaccinated) before they become sexually active," she said.

Cervical cancer is the second-most common cancer in women and their No. 2 cause of cancer deaths, resulting in about 3,000 deaths in the United States and nearly 300,000 around the world each year. At least half of sexually active men and women become infected with genital HPV at some point.

The immune system clears most such infections in a year or two, but several types of HPV can persist, cause cervical cancer or trigger other cancers in the genital area. There is no cure for HPV, but the cancers can be treated and an improved Pap test is catching more cervical cancer before it has spread.

Whitehouse Station-based Merck, hammered by slumping revenues and profits and facing roughly 5,000 lawsuits over its withdrawn painkiller Vioxx, is seeking to beat rival drug maker GlaxoSmithKline to market with the first cervical cancer vaccine.

GlaxoSmithKline did not return a call seeking comment, but has published research showing its vaccine against HPV 16 and 18 prevents persistent HPV infection. The Merck vaccine also reduces infection with HPV 6 and 11, which cause 90 percent of genital warts cases.

Merck plans by year's end to seek Food and Drug Administration approval to sell its vaccine for use by girls and young women.

"If all goes well, sometime in 2006 it should be on the market," Barr said.

Merck is continuing research on Gardasil and will soon report on four years of follow-up on women in the current study. The company also will explore whether the vaccine's effectiveness wanes over time. Barr noted that some women in the study developed dangerous precancerous lesions caused by HPV types other than 16 and 18.